



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

O. Haweal
#31
8/12/02

the Application
of:

DO NOT ENTER

OK TO ENTER

OK AS ENTERED

Serial No.: 09/198,004 Filed On: November 23, 1998) (Docket No. 116310.0032)

Edward L. Carver, Jr.) Group Art Unit: 1743
Steven J. Skiptunas)
)
APPARATUS AND) Examiner: L. Alexander
METHOD FOR)
MIXING FLUIDS)
FOR ANALYSIS)
)
)
09/198,004)
)

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Commissioner of Patents
Washington, D.C. 20231

RESPONSE TO FINAL OFFICE ACTION UNDER RULE 116

Dear Sir:

Claims 1, 3-6, 31 and 33-47 are pending in this application. In view of the following remarks, it is respectfully submitted that these claims are allowable.

Claims 1, 3-6, 31 and 33-47 stand rejected under 35 U.S.C. § 102(b) as being anticipated by EP 010733 ("EP '733"). The Examiner's grounds for rejection are hereinafter traversed and reconsideration is respectfully requested.

EP '733 does not teach or suggest the following structure as recited in independent claims 1 and 42:

means for combining at least one reagent-mixture component stream into at least one other reagent-mixture component stream for mixing the plurality of reagent-mixture components into a combined reagent-mixture stream;

means for forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality

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of reagent-mixture components in accordance with a flow-rate ratio of reagent-mixture components corresponding to each respective selected reagent mixture;

means for either chemically analyzing, or analyzing a particle distribution of, the selected reagent mixture in the combined reagent mixture stream.

Nor does EP '733 teach or suggest a method involving the functional recitations summarized above and recited in further detail in independent claim 31.

To the contrary, in the apparatus and method described in EP '733, the blood samples are first mixed in the reaction vessels 40, 42 and 44. More specifically, the first reaction vessel 40 contains the blood sample and appropriate reagent mixture for counting and sizing red blood cells and platelets, reaction vessel 42 contains the blood sample and appropriate reagent mixture for counting and sizing basophils, and reaction vessel 44 contains the blood sample and appropriate reagent mixture for sizing and counting all other white blood cells except basophils. (See, e.g., page 10, line 29 through page 11, line 12 of EP '733). The sheath fluid reservoirs 96, 98 and 100 each contain a sheath liquid that is optically compatible with the respective mixture contained in a corresponding reaction vessel 40, 42 or 44. (See, id.)

During operation, each sample-reagent mixture contained in a respective reaction vessel 40, 42, or 44 and the corresponding compatible sheath liquid contained in the respective sheath fluid reservoir 96, 98 or 100 are pumped through the flow cell 12. The sample-reagent mixtures contained in the reaction vessels 40, 42 and 44 are not pumped through the flow cell at the same time. Rather, only one sample-reagent mixture and corresponding sheath fluid are pumped through the flow cell at any one time. (See, e.g., page 4, lines 7-10, and lines 29-33 of EP '733).

In addition, the flow cell 12 does not combine the sample and sheath streams. Rather, EP '733 specifically teaches maintaining the sample and sheath fluid -- while being analyzed in the flow cell -- in two separate unmixed streams that are concentrically located at two different diameters. For example, EP '733 states: "the sheath stream flow cell 12 brings the sample and sheath streams introduced at inlets 26 and 28, respectively together to form a pair of concentric, substantially unmixed streams, with the sample stream at the center." (Page 7, lines 7-12 of EP '733, emphasis added). EP '733 further states: "This forms the concentric sample-sheath liquid streams through the flow cell under precisely controlled and coordinated, readily reproducible conditions of constant, and optimal, sample and sheath liquid stream diameters . . ." (EP '733 at page 14, lines 4-7, emphasis added). In addition, the concentric sample-sheath liquid streams are not mixed until after they are analyzed and upon exiting the flow cell through the flow cell outlet 30. Indeed, the very purpose of maintaining the separate, unmixed streams as taught by EP '733 is to facilitate analysis in the flow cell.

Thus, the clear and unambiguous teaching of EP '733 is to first premix the separate samples and reagents in the reaction vessels 40, 42 and 44, wherein each premixed sample-reagent mixture is defined by the respective test to be performed thereon. Then, to separately pump each reaction mixture through the flow cell 12 with its corresponding sheath fluid, and to maintain the reaction mixture and sheath fluid while being analyzed in the flow cell in two separate, unmixed streams that are concentrically located at different diameters.

Accordingly, EP '733 wholly fails to teach or suggest combining at least one reagent-mixture component stream into at least one other reagent-mixture component

stream for mixing the plurality of reagent-mixture components into a combined reagent mixture stream, and chemically analyzing, or analyzing a particle distribution of, the selected reagent mixture of the combined reagent mixture stream, as recited in the present independent claims. Rather, EP '733 premixes the sample-reagent mixtures in the reaction vessels, and does not combine any streams of reagent mixture components and, in turn, analyze any such combined reagent-mixture stream.

Moreover, EP '733 fails in any way to teach or suggest forming each of a plurality of different selected reagent mixtures in the combined reagent-mixture stream by adjusting the flow rate of at least one of a plurality of reagent-mixture components in accordance with a flow-rate ratio of reagent-mixture components corresponding to each respective selected reagent mixture, as further recited in the independent claims. Rather, EP '733 forms different selected reagent mixtures by pre-mixing them in the reaction vessels. There is simply no teaching or suggestion in EP '733 of forming such mixtures by combining reagent-mixture streams, much less adjusting the flow rate of the components in accordance with a flow-rate ratio corresponding to the selected reagent-mixture ratio, as further recited in the claims.

Accordingly, contrary to the Examiner's assertion at page 2 of the Action, EP '733 does not teach "multiple reagent component streams that are combined." Rather, as described above, in EP '733 only one reagent component stream is pumped at any one time through the flow cell 12. Moreover, each such reagent component stream is not mixed with its corresponding sheath fluid until after it is analyzed and it exits the flow cell as waste. In addition, it is respectfully submitted that the Examiner has misread at page 2 of the Action the last clause of claim 1. The last clause of claim 1 recites "means

for at least one of (i) chemically analyzing and (ii) analyzing a particle distribution of the selected reagent mixture of the combined reagent-mixture stream." The language "the selected reagent mixture of the combined reagent-mixture stream" modifies both "(i) chemically analyzing" and "(ii) analyzing a particle distribution of".

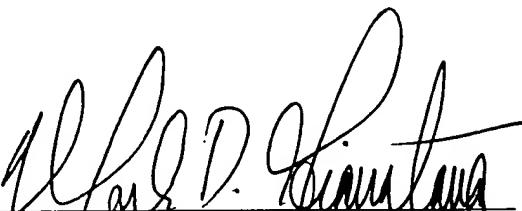
Accordingly, it is respectfully submitted that EP '733 wholly fails to teach or suggest the invention as recited in independent claims 1, 31 and 42, for at least these reasons. Because claims 3-6, 33-41 and 43-47 each depend from, and therefore include all of the limitations of one of the independent claims, it is respectfully submitted that the dependent claims are neither anticipated nor rendered obvious over EP '733 for at least the same reasons as set forth above in connection with the independent claims, and for reciting additional patentable subject matter.

No fee in addition to that submitted herewith is believed to be required. However, if an additional fee is required, or otherwise if necessary to cover any deficiency in fees paid, authorization is hereby given to charge our deposit account no. 50-1631.

The Examiner is respectfully requested to call the undersigned at the telephone

number below if he has any questions in connection with any of the issues herein, or otherwise if it would facilitate the examination of this application.

Respectfully submitted,

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Date: July 29, 2002

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